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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,114	08/18/98	PRICE	I P8129-8004

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ARENT, FOX, KINTNER, PLOTKIN & KAHN, P.L.
1050 CONNECTICUT AVENUE, N.W.
SUITE 600
WASHINGTON DC 20036-5339

EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

06/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,114

Applicant(s)

PRICE, IAN ASHLEY

Examiner

Alysia Berman

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the request for extension of time, amendment and information disclosure statement filed 10 March 2000 and the change of address filed 13 March 2000. Claims 1, 2, 4, 5, 7, 9, 11-14, 16, 18-20, 22, 25 and 26 have been amended. Claims 27-37 have been added. Claims 1-37 are pending. The status of the application is as follows:

Information Disclosure Statement

2. The information disclosure statement filed on 9 March 2000 does not fully comply with the requirements of 37 CFR 1.98 because: there is no documentation of the date of the British Pharmacopocia reference and the paper by Hannula et al. entitled *Effects of pH regulators used as additives on the bioavailability of ibuprofen from hard gelatin capsules*. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b). Failure to timely comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-8, 10-13, 16-18, 20-22, 24-29, 31, 32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,565,613 (Geisslinger et al. '613) in view of US 5,262,179 (Gregory et al. '179), and further in view of US 4,844,907 (Elger et al. '907).

See paper no. 7. Consisting essentially of limits the scope of the claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition. *Ex parte Davis*, supra; *In re Janakirama-Rao*, 317 F2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of his composition – i.e. a showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F2d 870, 143 USPQ 256 (CCPA 1964). Therefore, applicant has the burden of showing that the additional ingredients in the prior art compositions are detrimental to the instant invention.

5. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,565,613 ('613) in view of US 5,631,296 (Birrenbach et al. '296), and further in view of WO 89/02266 (Denton '266).

See paper no. 7. For hydroxypropylmethyl cellulose, lubricants such as magnesium stearate and flow aid such as colloidal silicon dioxide, *inter alia*, see column 5, lines 42-50. Consisting essentially of limits the scope of the claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition. *Ex parte Davis*, supra; *In re Janakirama-Rao*, 317 F2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference composition are excluded by the recitation

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of “consisting essentially of”, applicant has the burden of showing the basic and novel characteristics of his composition – i.e. a showing that the introduction of these components would materially change the characteristics of applicant’s composition. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Therefore, applicant has the burden of showing that the additional ingredients in the prior art compositions are detrimental to the instant invention.

Response to Arguments

6. Applicant's arguments filed 10 March 2000 have been fully considered but they are not persuasive.

7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The idea of combining them flows logically from their having been individually taught in the prior art. *In re Crockett*, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). In this case, the references are useful for the same purpose, the oral administration of ibuprofen.

8. In response to applicant's argument that the references fail to show certain features of applicant’s invention, it is noted that the features upon which applicant relies (i.e., a tablet) are

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not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on 8:00-4:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703/308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.



Alysia Berman
Patent Examiner
June 13, 2000



DIANA DUDASH
PRIMARY EXAMINER
GROUP 1600